REMARKS

Claims 1-23 are pending herein and are presented for examination.

Rejection Under UMEMURA in View of TROGOLO and MCGLOTHLIN

The Examiner has rejected Claims 1-23 under 35 U.S.C. 103(a) based on Umemura et al. (U.S. Patent No. 4,902,503) ("UMEMURA") in view of Trogolo et al (U.S. Patent Application Publication No. 2003/0118664 ("TROGOLO") and McGlothlin et al. (U.S. Patent No 6,329,444) ("MCGLOTHLIN"). This rejection is respectfully traversed.

The present invention is directed to medical articles that comprise an antimicrobial region, which antimicrobial region comprises release-modulating *dispersed microparticles* within a latex polymer. The release-modulating microparticles comprise an antimicrobial agent and are adapted to release the antimicrobial agent.

UMEMURA discloses two types of antimicrobial latex compositions.

1) The first type contains a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver. This first type utilizes a latex, e.g., natural rubber latex, and a silver protein complex, protein-silver, dissolved in the aqueous phase of the latexes. It is important to note that this first type of antimicrobial latex composition requires the silver to be water soluble. (See the Abstract; and specification at col. 2, line 60; col. 4, lines 45-48; col. 4, lines 54-57; and col. 5, lines 54-56.) In contrast to the present invention, this first type does not describe:

A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed. [emphasis added]

2) The second type uses a homogeneous blend of a cationic natural or synthetic rubber and soluble silver compounds, e.g., silver nitrate, among others. (See, e.g., Abstract; and specification at col. 4, lines 49-53.) As with the protein silver, the water-soluble silver compounds are dissolved in the aqueous phase. (See, e.g., col. 8, lines 41-42.) As noted above for the first type, UMEMURA lacks any teaching of "*release-modulating microparticles*

disposed within a latex polymer," and *"microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed"* as claimed.

Thus, both types of embodiments described UMEMURA lack several of the key components of the invention. UMEMURA lacks any teaching of "release-modulating *microparticles* disposed within a latex polymer," as claimed. To the contrary, it is essential that the antimicrobial compound be *dissolved* in the aqueous phase of the latex. This is a direct teaching away from the present invention. In re Baird, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994); also see the cases cited in MPEP 2141.02 VI and the cases cited therein.

These key deficiencies are not provided by any of the other cited references.

The Examiner has not addressed these key deficiencies in the current Office Action. The Examiner has merely responded that the term "latex" as used by Applicant is far broader than the literal definition and encompasses the polymers of UMEMURA. This statement is not clear and requires further explanation by the Examiner as to the relevance of the point being discussed. Regardless of the definition of "latex", UMEMURA still lacks the elements of "*release-modulating microparticles disposed within a latex polymer*," and *"microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed"* as claimed.

Applicant again notes that UMEMURA (col. 2, lines 18-31) recites that a latex, such as a natural rubber latex dispersed in water, is a highly unstable system. Consequently, when an aqueous solution containing a highly soluble silver compound is added to a latex at a high concentration in order to give a high silver concentration in the resulting matrix material, the silver nitrate has been observed to break the system. Moreover, when silver carbonate, which has an extremely low solubility in water, is added, the stable latex dispersion system is also broken and aggregation is observed. Therefore, it has been impossible to obtain a stable latex composition.

UMEMURA attempts to solve this stability problem by its technique as described at col. 2, lines 62-68:

Accordingly, the crux of the present invention resides in an antimicrobial latex composition prepared by blending silver protein with a natural rubber latex or a synthetic polymer latex, and in an antimicrobial latex composition prepared by blending water-soluble silver compound with a cationic natural rubber latex or a cationic synthetic polymer latex.

There is no teaching or suggestion of the present invention, in particular the features of "*release-modulating **microparticles** disposed within a latex polymer*," and, even more particularly, of "*microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed*" as claimed.

The Examiner adds TROGOLO in an attempt to overcome the deficiencies in UMEMURA. TROGOLO teaches microcapsules comprising an antimicrobial agent, typically in the form of a particle or particles encapsulated within a hydrophilic polymer (See Summary of the Invention). TROGOLO also teaches a method of preparing an antimicrobial resin by incorporating an antimicrobial microcapsule into a polymer matrix.

TROGOLO, however, does not teach or suggest that the antimicrobial microcapsules can be deposed in a latex polymer. In fact, TROGOLO does not appear to disclose any type of latex whatsoever. Contrary to the Office Action, this assessment of TROGOLO is applicable to the term "latex" even as it is used by Applicant. As defined in paragraph [0021] of the current specification, a "latex," is an aqueous polymer dispersion. By "aqueous polymer dispersion" is meant a dispersion of polymer particles in a water-containing fluid. Thus, as indicated in the Office Action, the term "latex" as defined by Applicant is relatively broad as it is not restricted to a particular polymer. However, the term is not without limitation in that it requires "a dispersion of polymer particles in a water-containing fluid". Nothing of the sort is taught by TROGOLO.

TROGOLO actually teaches away from using latexes at paragraph [0081], where the advantages of thermal/melt processing are disclosed, which advantages may be considered unique to the process disclosed and essential to the enhanced antimicrobial functioning of the resulting articles. See, e.g., MPEP 2141.02 VI and the cases cited therein.

Thus, there is no reason that one skilled in the art would combine the antimicrobial microcapsules of TROGOLO with UMEMURA, and UMEMURA actually teaches away from such antimicrobial microcapsules by requiring the use of soluble antimicrobial agents.

The rejection relies on the combination of two references each of which does not teach the elements of the claimed invention and which, by reason of their individual subject matter are not combinable. Thus, at the very least, the combination would have been unwarranted by the

disclosures in the references. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984), *Carl Schenk, A.G. v. Norton Corporation*, 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983), *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959), MPEP 2143.01, last paragraph. Consequently, the rejection could only have been based on undue hindsight reconstruction of the references. MPEP 2142, second paragraph, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Moreover, even if the references were combined, there would not be a reasonable expectation of success. For example, one of ordinary skill would not reasonably expect success in using the antimicrobial microcapsules of TROGOLO in the latex-based process of UMEMURA, because UMEMURA requires the use of a dissolved antimicrobial agent. Again, the combination of the teachings of UMEMURA and TROGOLO is directly contrary to what one of ordinary skill would have done with any expectation of success. See MPEP 2143.02 and the cases cited therein.

MCGLOTHLIN describes medical devices of synthetic rubber are prepared from cis-1,4-polyisoprene by dip molding without the use of sulfur containing components. The relevance, if any, to the current invention is remote. MCGLOTHLIN has been relied on only as merely showing that coating of medical devices through dip molding is established in the art using one of the polymers defined as a latex. There is no teaching in MCGLOTHLIN, however, pertaining to antimicrobials, either soluble or as microparticles. Like UMEMURA and TROGOLO there is nothing in MCGLOTHLIN that teaches or suggests "*release-modulating microparticles disposed within a latex polymer*," and, even more particularly, of "*microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed*" as claimed.

Thus, this reference adds nothing relevant to the combination of references discussed above.

Reconsideration and withdrawal of the rejection of claims 1-23 under 35 U.S.C. 103 is respectfully requested.

CONCLUSION

Applicants submit that Claims 1-23 are in condition for allowance, early notification of which is earnestly solicited. It is believed that this Response is being submitted in time for an Advisory Action should the Examiner require further changes to the Claims. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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